

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims. In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better condition for appeal.

Issues Under 35 U.S.C. 112, First Paragraph

1. Written Description

The Examiner has rejected claims 18-19 and 22-30 under 35 U.S.C. § 112, first paragraph asserting that the present specification fails to contain a written description which would reasonably convey to one of skill in the art that Applicants had possession of the claimed invention at the time of filing the application. Applicants respectfully traverse.

The Examiner asserts that the gene of 4.4 Kbp and primers therefor are based upon corn and not any other species, and thus, the claims do not allegedly satisfy § 112, written description requirements. However, Applicants respectfully submit that this is not the only property which is claimed for the present nucleic acid sequences. In particular, Applicants draw the Examiner's attention to the fact that the nucleic acid sequence codes for an aldehyde oxidase enzyme which enzyme is capable of oxidizing an aldehyde compound to a carboxylic acid. Thus, in order for a nucleotide sequence to fall within the scope of the present

claims, it must satisfy the functional requirement of the encoded enzyme recited. Concerning this activity, the present specification provides a description for ascertaining whether or not the encoded enzyme satisfies the aldehyde oxidase activity recited in the claims. One of ordinary skill in the art would fully recognize that Applicants were in possession of this claimed invention.

Moreover, further structure is imposed upon the above 4.4 kbp limitation and the aldehyde oxidase functional limitation. Limitation (e) requires specific PCR primers, thus adding an additional layer of physical properties. In particular, the nucleotide sequence must be one which can be amplified by using the specific primers. Moreover, the origin of the nucleotide sequence is a plant. Each of the above four limitations must be taken into consideration.

The Examiner further asserts that while the "Tm" value is critical in PCR reactions, so are other parameters such as denaturation and extension. The Examiner asserts that if these steps are not done properly according to the nucleotide sequence used in the PCR reaction, many false positives will be produced. The Examiner asserts that if the primers are not correctly designed according to sequence that is going to be isolated, a "shotgun" approach will result.

Applicants agree with the Examiner that such parameters are important, however, it does not necessarily follow that the

present application fails to provide an adequate written description for these parameters. Applicants remind the Examiner that a patent need not teach, and preferably omits, what is well known in the art. Spectra-Physics Inc. v. Coherent Inc., 3 USPQ2d 1737 (CAFC 1987).

The factors relating to the PCR reaction conditions are based upon the nucleotide sequence of primers utilized. The annealing temperature is dictated by the nucleotide sequence of the primers, the sequence of which is recited in the claims.. Moreover, the other reaction conditions such as time for annealing, temperature and time for denaturation, and temperature and time for extension depend only upon the property of DNA polymerases themselves used by one of ordinary skill in the art. In practice, one of ordinary skill in the art determines the reaction conditions and operates the reaction in accordance with the protocol attached to publicly available PCR kits.

Accordingly, the disclosure of the nucleotide sequence of the primers provides adequate description to one of ordinary skill in the art to properly conduct the PCR reaction for a gene derived from any plant, not just maize. As further evidence, Applicants submit herewith the following material: CLONTECH Lab., Inc. (1997), MarathonTM cDNA Amplification Kit User Manual, page 35: XIII. Generation of Full-Length cDNA by PCR. In the attached material, it is discussed that 10 kbp cDNA can be easily amplified. Moreover, the manner of preparing the reaction

solution and the reaction conditions is specified in detail. It is evident that there is no room for alteration by individual decisions of users except through the nucleotide sequence of primers utilized. Accordingly, applicability of PCR reaction conditions does not depend upon a description of the plant to be used. Thus, trial and error does not enter into the PCR reaction as suggested by the Examiner. Applicants respectfully submit that the above is fully understood by one of ordinary skill in the art. Thus, one of ordinary skill in the art would fully understand that Applicants were in possession of the claimed invention at the time of filing the application. Moreover, there is no disclosure that the claimed invention should be limited to that of a maize origin since the present application provides a full written description for the use of any plant.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. 112, first paragraph, based upon an allegedly insufficient written description.

## 2. Enablement Requirement

The Examiner has rejected claims 18-19 and 22-30 under 35 U.S.C. 112, first paragraph, asserting that the present specification, while being enabling for isolation of sequences according SEQ ID NO 1-4, does not provide enablement for the isolation of an aldehyde oxidase gene having a nucleotide sequence

which encodes an amino acid sequence of 4.4 kbp gene obtainable from a plant using a combination of PCR primers that are selected from a group consisting of SEQ ID NO 7-15 or for the process of controlling production of aldehyde oxidase in transformed host cells. Applicants respectfully traverse.

Applicants respectfully submit that the claimed invention does not cover all genes encoding an enzymes having aldehyde oxidase activity. Further requirements, such as gene with a specific size (4.4 kbp), which is derived from a plant, and which can amplified by using specific primers, are required. The present specification is fully enabling for this subject matter.

The Examiner asserts that a specification based solely on the corn aldehyde oxidase gene cannot enable and provide an adequate description for all genes from any plant species. Moreover, the Examiner asserts that neither the present specification nor the prior art teaches that the nucleotide sequence of aldehyde oxidase from corn can be successfully used to identify non-corn genes without undue experimentation. However, Applicants submit that the Examiners understandings are in error. In particular, a gene derived from plants other than maize, isolated by using PCR primers disclosed in the present invention is definitively disclosed and enabled. This disclosure satisfied by a combination of (1) the physical property of the 4.4 kbp gene, (2) the physical property based upon a nucleotide sequence which can be amplified using specific primers, (3) the origin defined as being from a

plant, and (4) the chemical properties based upon the aldehyde oxidase activity.

Applicants point out to the Examiner that the issue as to whether or not the disclosed primers can be used for amplifying genes derived from plants other than maize is distinct from the issue of whether or not a concrete disclosure of other plants besides maize exists. Of importance is the issue of whether or not the nucleotide sequence derived from a plant origin other than maize includes a nucleotide sequence corresponding to that of the present primers. This fact may be easily determined without undue experimentation by using the methods disclosed in the present specification. Accordingly, one of ordinary skilled in the art is fully enabled to the scope of the presently claimed subject matter.

Applicants remind the Examiner that the specification is not required to teach every detail of the invention. The fact that experimentation may be complex does not necessarily make it undue if a person skilled in the art typically engages in such experimentation. In re Borkowski, 164 USPQ 642, 645 (CCPA 1970). Moreover, the determination of whether or not an invention requires undue experimentation is not based upon a single factor. Rather, several factors including (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented in the application, (3) the presence or absence of working examples of the invention in the application, (4) the

nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability in the art, and (8) the breadth of the claimed invention, must also be taken into consideration. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1998).

Applicants respectfully submit that taking all of the above factors into consideration, the present claims are fully enabled. Moreover, Applicants are not required to create actual physical samples of genes derived from other plants. Applicants have already provided an example for maize. Utilizing this example, the disclosure of the present invention, and the general skill in the art, undue experimentation would not be required for one of ordinary skill in the art to practice the invention to all plants. In fact, the specification need not contain a working example if the invention is otherwise disclosed in such manner that one skilled in the art would be able to practice the invention without undue experimentation. In re Borkowski, 164 USPQ at 645.

In view of the above, Applicants respectfully request that the Examiner withdraw the enablement rejection under 35 U.S.C. 112, first paragraph and allow the currently pending claims.

In the event that the Examiner does not deem the present application in condition for allowance, he is requested to contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP to discuss this matter further.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to October 25, 2000 in which to file a reply to the Office Action. The required fee of \$890.00 is being filed concurrently with the Notice of Appeal.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Raymond C. Stewart  
Reg. No. 21,066

*Cam*  
RCS/CAM/gh

P. O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

Enclosure: CLONTECH Lab., Inc. PCR Manual papers.